

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

INTERNATIONAL DAIRY FOODS	:	Case Nos. 2:08-CV-628, -629
ASSOCIATION,	:	(consolidated)
	:	
and	:	JUDGE GRAHAM
	:	
	:	MAGISTRATE JUDGE KING
	:	
ORGANIC TRADE ASSOCIATION,	:	
	:	
Plaintiffs,	:	<u>MOTION OF DEFENDANT FOR</u>
	:	<u>SUMMARY JUDGMENT AND</u>
	:	<u>MEMORANDUM OF DEFENDANT</u>
v.	:	<u>IN OPPOSITION TO PLAINTIFFS'</u>
	:	<u>MOTIONS FOR SUMMARY</u>
ROBERT J. BOGGS, Director,	:	<u>JUDGMENT</u>
Ohio Department of Agriculture,	:	
	:	
Defendant.	:	

Pursuant to FED. R. CIV. P. 56, Defendant Robert J. Boggs, Director of the Ohio Department of Agriculture ("Director"), moves for summary judgment on all claims. Defendant further opposes the motions for summary judgment filed by Plaintiffs International Dairy Foods Association ("IDFA") (Doc. 21, Case No. 2:08-CV-628) and Organic Trade Association ("OTA") (Doc. 18, Case No. 2:08-CV-629), respectively. Supporting affidavits and memorandum are attached hereto.

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Ohio Admin. Code § 901:11-8-01 (the “Rule”) does not violate the First Amendment of the United States Constitution. The Rule regulates dairy labels in Ohio in two ways: it requires that production claims regarding the use of recombinant bovine somatotropin (rBST) be verified and that they be accompanied by a truthful statement that the U.S. Food and Drug Administration (FDA) has not found any significant difference in the milk from cows that have or have not been supplemented with rBST. Production claims which are truthful and not misleading are not prohibited by the Rule. Composition claims which are false or inherently misleading are prohibited, including claims regarding the presence of hormones, antibiotics, or pesticides in the product itself.

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Regulations which require the inclusion of truthful information on product labels do not violate the free speech rights of the labeling entity so long as the regulation is reasonably related to a legitimate state interest. *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985); *National Elec. Mfrs. Ass’n v. Sorrell*, 272 F.3d 104 (2d Cir. 2001). The free speech interest of a party in not providing truthful information is minimal and is overridden by the state’s interest in assuring that consumers receive accurate information about the food they consume. *Int’l Dairy Foods Ass’n v. Amestoy*, 92 F.3d 67 (2d Cir. 1996) is inapplicable because the Rule is designed to prevent consumer deception.

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False or misleading commercial speech is not protected under the First Amendment. *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm’n of New York*, 447 U.S. 557 (1980). The label claims regulated by the Rule are either false or inherently misleading, and are properly restricted or subjected to disclosure requirements under the Rule in order to prevent Ohio consumers from being misled.

3. **Even if the label claims addressed in the Rule were not misleading, the Rule does not violate the First Amendment because the Rule directly advances a substantial state interest in a narrowly drawn fashion.....14**

Under *Central Hudson*, commercial speech which is not false or misleading may nevertheless be regulated by the state if the governmental interest is substantial, the regulation directly advances the governmental interest asserted, and the regulation is not more extensive than is necessary to serve that interest. 447 U.S. at 566. The Rule passes this test in that the state has a substantial interest in assuring that consumers receive accurate information of the food they eat; the Rule directly advances the interest by preventing dairy labels from making false or misleading statements regarding the production and composition of the product; and the Rule is narrowly tailored to accomplish this purpose.

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The Rule does not violate the dormant Commerce Clause of the United States Constitution, by directly regulating interstate commerce in dairy products outside Ohio, imposing inconsistent regulatory burdens on interstate commerce, discriminating against out-of-state dairy industry members in favor of Ohio farmers, or imposing a burden on interstate commerce that is unreasonable compared to the local benefits.

1. **The Rule was not enacted for a protectionist purpose, does not discriminate in any way against out-of-state economic interests, and places no direct burdens on interstate commerce.....18**

The Rule is completely even-handed in its regulation of both in-state and out-of-state economic interests. The Rule was not enacted for any protectionist purpose and places no direct burdens on interstate commerce, nor does the Rule attempt to project Ohio's regulatory scheme into the commerce of other states. Any impact of the Rule on interstate commerce is indirect and incidental. Courts have long recognized that the exercise of the state's police power to protect the welfare of its citizens routinely and unavoidably has such impact on interstate commerce, and the regulations are not rendered invalid as a result of this indirect effect. *Milk Control Bd. v. Eisenberg Farm Prods.*, 306 U.S. 346 (1939). While Plaintiffs reply on *Healy v. The Beer Institute*, 491 U.S. 324 (1989), that case is inapposite because the Rule does not attempt to control extraterritorial commercial transactions in other states. Also inapposite is *Hunt v. Washington State Apple Adver. Comm'n*, 432 U.S. 333 (1977), because Ohio's law is non-discriminatory, does not effect a "downgrade" on out-of-state products, and there is no disparity between Ohio dairy products and out-of-state dairy products with regard to the manner in which they are packaged for sale.

2. **Any incidental burden which the Rule may place upon interstate commerce is not clearly excessive in relation to the local benefit.....**24

An even-handed rule which only incidentally affects interstate commerce does not violate the dormant Commerce Clause unless the adverse impact substantially outweighs the local benefit advanced by the regulation. *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970). Any impact of the Rule on interstate commerce is incidental and slight, and is greatly outweighed by the local benefit of protecting Ohio consumers from false and misleading dairy labels.

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1. **Congressional regulation of organic food production, handling, and labeling is not so sweeping as to preclude states from exercising their police powers to protect consumers from the false or misleading labeling of dairy products.....**29

The Organic Foods Production Act (“OFPA”) was enacted solely to regulate the use of the term “organic” on food labels, and was never intended to preclude the states from exercising their traditional role of regulating label claims so as to prevent consumers from receiving false or misleading claims about their food. Regulation of food labeling is a field traditionally occupied jointly by the states and the federal government. *Kellogg, Co. v. Mattox*, 763 F. Supp. 1369 (W.D. Tx. 1991). The Rule is entirely consistent with the purpose of OFPA and with the regulatory scheme enforced FDA. OTA does not show that the federal regulatory schemes leave no room for the states to use their police powers to protect consumers against false and misleading dairy labeling. *See Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132 (1963).

2. **The Rule does not conflict with the OFPA’s purposes of establishing national organic standards, because there is no evidence Congress intended to prevent states from protecting consumers from false and misleading labels on organic products.....**32

The Rule does not stand as an obstacle to the federal program of regulating the use of the term “organic” under the OFPA. This case is a far cry from *Lever Bros. Co. v. Maurer*, 712 F. Supp. 645 (S.D. Ohio 1999), because the Rule does not prohibit the making of any claim or the use of any term required by the OFPA regulation. The Rule also is consistent with and does not create any conflict with OFPA certification requirements.

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I. INTRODUCTION

In an effort to protect consumers from false and misleading information on dairy labels, Ohio enacted an emergency rule regulating certain statements on dairy labels. Since there is no evidence of any significant difference between milk produced from cows supplemented with the hormone rbST and milk produced from cows not supplemented with rbST, the Ohio Rule prohibits such statements as “rbST Free” and “Hormone Free.” The Rule also permits labels indicating that the milk is from cows not supplemented with rbST, but if the labeler sufficiently documents its claim, and the label contains a statement (or its equivalent) that the FDA “has determined that there is no significant difference has been shown between milk produced from cows rbST-supplemented and non-rbST-supplemented cows” in the exact same font style, case, and color, and at least half the size as the dairy label.

Plaintiffs have sued the Director, and moved for summary judgment, claiming the Rule violates both their commercial speech rights under the First Amendment, and the dormant Commerce Clause. OTA also claims the Rule is preempted by federal law and is unconstitutionally vague.

Plaintiffs’ motions for summary judgment should be denied. The Rule does not violate Plaintiffs’ commercial speech rights because it prohibits false and misleading composition claims on dairy labels, and permits truthful production claims. The Rule’s disclosure requirements meet the applicable “reasonableness” standard for mandatory disclosure of truthful information set forth in *Zauderer v. Office of Disciplinary Counsel*. The Rule also satisfies *Central Hudson* because false and misleading speech is not protected by the First Amendment. Further, the Rule is narrowly tailored to directly

advance Ohio's substantial government interest in protecting consumers from false and misleading labeling of food products.

The Rule does not offend the dormant Commerce Clause because it has no discriminatory intent or effect; it applies evenhandedly to both in-state and out-of-state dairy producers and handlers. Any impact the Rule has on interstate commerce is an indirect and incidental effect of the exercise of Ohio's state police powers. Such a slight, incidental burden is greatly outweighed by the local benefit of protecting Ohio consumers from false and misleading dairy labeling.

Further, the Rule is not preempted by the Organic Foods Production Act ("OFPA") or its attendant regulations. The OFPA's national organic program is not so sweeping as to leave no room for the states from using their traditional police powers to protect consumers by regulating food labels. Also, there is no conflict preemption because the Rule does not obstruct or frustrate the purposes of OFPA certification rules.

The Rule's use of the word "may" does not make it unconstitutionally vague. Where the public interest is involved, or the public interest is furthered – as is the case here—the word "may" is construed as mandatory. "May," as used in the Rule is also construed as mandatory because it expresses ability or power. Finally, the Court should construe to word "may" as mandatory to avoid any issue of constitutionality.

Accordingly, because Plaintiffs' constitutional claims are without merit, this Court should deny Plaintiffs' motions for summary judgment and grant the Director's motion for summary judgment.

II. STATEMENT OF FACTS

Responding to the need to maximize consumer information and consumer choice in dairy purchases, Ohio Governor Ted Strickland issued Executive Order 2008-03S on February 7, 2008, which immediately adopted a rule to define what constitutes false and misleading labels on milk and milk products. (Attachment 1.) The Order recognizes that, since 1994, the United States Food and Drug Administration (“FDA”) has allowed the use of the hormone recombinant bovine somatotropin (“rbST”) in dairy cows that it “has determined that there is no significant difference between milk produced from cows supplemented with rbST and milk produced from cows not supplemented with rbST.” (Exec. Order 2008-03S ¶ 2.) Further recognizing that there is no current scientifically reliable means to test for rbST in milk (*id.* ¶ 5), the governor authorized the Ohio Department of Agriculture (“ODA”) to immediately adopt a rule on what constitutes false and misleading labels on dairy products, require dairy producers who claim they do not use rbST to submit appropriate documentation for ODA review, and create labels consistent with the FDA’s findings on rbST. (*Id.* ¶ 5.) The Order was in effect until May 7, 2008. (*Id.* ¶ 11.)

The Director solicited comments from dairy consumers, processors, scientists and other interested parties, and in doing so took the following steps: convened a listening session to discuss dairy labeling, appointed an advisory committee on dairy labeling with as broad a representation of willing participants as possible, conducted a public hearing to receive public comments on the emergency rule, made certain changes to the proposed rule and submitted the proposed rule to the Ohio Joint Committee on Agency Rule Review (“JCARR”), and conducted a second public hearing for comments on the

proposed rule. (Attachment 2, Affidavit of Director Robert J. Boggs ¶ 3(A)-(F).) On April 11, 2008, ODA sent the modified rule to JCARR for review, and obtained estimates from large, medium-sized, and small dairy processors of the costs which the processors anticipated were needed to comply with the rule. (Attachment 3, Affidavit of Lewis Jones ¶ 5.) For large processors, the cost estimate was \$300-\$400 per label; for medium-sized processors, \$300-\$350 per label; and for small processors, \$250 per label. (*Id.*)

The final, revised version of the rule was adopted May 12, 2008, and became effective May 22, 2008. (*Id.* ¶ 6; Boggs Affidavit ¶ 6.) The rule is codified at Ohio Admin.Code § 901:11-8-01 (hereinafter, “the Rule.”) (Boggs Affidavit ¶ 7.) From the introduction of the emergency rule to enactment of the final Rule, the ODA has received numerous dairy labels for review and approval, of which 42 labels (from 11 firms) have been approved. (Jones Affidavit ¶ 6.)

The Rule is intended “to ensure that Ohio consumers receive truthful and non-misleading information regarding the dairy products that they consume.” (Boggs Affidavit ¶ 7.) The Rule is not intended to discriminate against out-of-state interests, does not distinguish in its label requirements based upon where the milk was produced or the dairy product was processed, or to advance the interests of Monsanto Company or any other individual business entity. (*Id.*)

III. STANDARD OF REVIEW

Summary judgment is appropriate when no genuine issues of material fact exist and the moving party is entitled to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986) (citing FED. R. CIV. P. 56(c)). To avoid summary judgment, the non-moving party “must do more than simply show that there is some

metaphysical doubt as to the material facts.” *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). The existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986). Rather, there must be a dispute over facts that will affect the outcome of the suit. *Id.* at 248. The mere existence of a scintilla of evidence in support of the non-moving party’s position is not sufficient; there must be evidence on which the jury could reasonably find for the non-moving party. *Copeland v. Machulis*, 57 F.3d 476, 479 (6th Cir. 1995).

IV. ARGUMENT

A. The Rule does not violate Plaintiffs' commercial free speech rights.

Plaintiffs assert that Ohio Admin. Code § 901:11-8-01 ("the Rule") improperly bans and/or restricts commercial speech with regard to certain claims which Plaintiffs wish to make on dairy labels regarding the non-use of rbST and similar claims. As explained below, this argument is without merit.

The Rule draws a distinction between composition claims and production claims. “Composition” claims concern the content of the final product itself. *See* Ohio Admin.Code § 901:11-8-01(C)-(D). “Production” claims concern the manner in which the milk was produced, including products given (or not given) to the dairy cows which produced the milk. *See id.* § 901:11-8-01(B). As the following legal discussion illustrates, while the entire Rule fully comports with the requirements of the First Amendment, the distinction drawn between the two types of claims is meaningful in determining the approach required to assess the Rule’s constitutionality.

For composition claims, the Rule prohibits such claims with regard to hormones, *id.* § 901:11-8-01(C), and to substances which are not permitted by the United States Department of Agriculture (“USDA”) to be present in *any* milk, such as antibiotics and pesticides. *Id.* § 901:11-8-01(D). The basis for these restrictions is that such claims are inherently misleading, and in some cases flatly false.

Milk cannot be produced without hormones, and all milk contains the cows’ natural growth hormone, bovine somatotropin (BST). Obviously, such claims as “hormone free” or “no hormones” are therefore simply false. Moreover, given existing technology, it is currently impossible to test milk to determine whether the hormones present are natural hormones or recombinant hormones (such as rbST). Whereas production claims are verifiable to a reasonable degree, as discussed below, composition claims regarding rbST and kindred compounds are *impossible* to verify. This fact creates an unacceptable risk of misleading consumers regarding the content of the dairy products they consume.

Compounds such as antibiotics and pesticides, on the other hand, are largely detectable in milk. Indeed, all milk is routinely tested for antibiotics, and the presence of any antibiotic in any amount renders the milk unacceptable for consumption. Pesticides can also be detected through testing, although cost considerations prevent the routine testing of each batch of milk. The Rule prohibits composition claims regarding these compounds not because of the impossibility of verification and enforcement (as with recombinant hormones), but because they are banned from *all* milk, whether organically or inorganically produced, or from herds supplemented with rbST or from herds that are not supplemented. While presumably true, such claims are nevertheless misleading

because they create a false impression that a competitor's dairy product not so labeled might contain such prohibited compounds.

For production claims, the Rule takes an entirely different approach, and for good reason. Plaintiffs' arguments that the Rule prohibits truthful and non-misleading production claims are emphatically incorrect. To the contrary, in the interest of facilitating the flow of such information to consumers (when desired), the Rule *allows* a processor to label the product as coming from cows not treated with rbST. The only restriction is that the claim must be verified, and it must be accompanied by a statement (in a prescribed format that ensures ready visibility to consumers) that the Food and Drug Administration ("FDA") has determined that no significant difference has been shown between milk derived from rbST-supplemented and non-rbST-supplemented cows. *Id.* § 901:11-8-01(B)(2). As discussed below, this approach ensures that truthful commercial speech is facilitated in a manner which reasonably protects consumers from misleading information.

1. The Rule's disclosure requirements regarding production claims satisfy the applicable reasonableness standard for mandatory disclosure of truthful information.

Plaintiffs' assertion that the appropriate standard of review of the Rule's constitutionality under the First Amendment is the test set forth in *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of New York*, 447 U.S. 557 (1980), is only partially true. The Rule's mandatory disclosure requirements on dairy labels are properly assessed under the lesser "reasonableness" standard set forth in *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985).

The *Central Hudson* test for commercial speech is as follows:

In commercial speech cases . . . a four-part analysis has developed. At the outset, we must determine whether the expression is protected by the First Amendment. For commercial speech to come within that provision, it at least must concern lawful activity and not be misleading. Next, we ask whether the asserted governmental interest is substantial. If both inquiries yield positive answers, we must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest.

447 U.S. at 566. While the Rule does pass muster under a *Central Hudson* analysis because it regulates misleading statements, as discussed below, the portion of the Rule mandating the FDA-disclosure language whenever rbST production claims are made is held to the lower *Zauderer*-review.

As noted *supra*, the Rule does not prohibit truthful and non-misleading production claims with regard to the use or non-use of rbST in the dairy cows producing the milk. Rather, the Rule allows such claims if they are accompanied by the clarifying FDA supplemental statement. Accordingly, this portion of the Rule does not ban commercial speech, but affirmatively requires a truthful disclosure to accompany the speech. This mandatory disclosure requirement is properly assessed under *Zauderer*.

In *Zauderer*, one of the issues considered by the Court was an Ohio requirement that an attorney advertising his willingness to represent clients on a contingent-fee basis must also disclose the fact that the client may be responsible for expenses even if the case fails. In upholding this requirement under a First Amendment challenge, the *Zauderer* Court clearly explained the standard that properly applies to such mandatory disclosure requirements:

[*Zauderer*] overlooks material differences between disclosure requirements and outright prohibitions on speech. In requiring attorneys who advertise their willingness to represent clients on a contingent-fee basis to state that the client may have to bear certain expenses even if he loses, Ohio has not attempted to prevent attorneys from conveying

information to the public; it has only required them to provide somewhat more information than they might otherwise be inclined to present. We have, to be sure, held that in some instances compulsion to speak may be as violative of the First Amendment as prohibitions on speech. . . . Indeed, . . . the Court [has gone] so far as to state that “involuntary affirmation could be commanded only on even more immediate and urgent grounds than silence.” . . .

But the interests at stake in this case are not of the same order as those discussed [above]. Ohio has not attempted to “prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion or force citizens to confess by word or act their faith therein.” . . . *The State has attempted only to prescribe what shall be orthodox in commercial advertising*, and its prescription has taken the form of a requirement that appellant include in his advertising purely factual and uncontroversial information about the terms under which his services will be available. Because the extension of First Amendment protection to commercial speech is justified principally by the value to consumers of the information such speech provides . . . *appellant's constitutionally protected interest in not providing any particular factual information in his advertising is minimal*. Thus, in virtually all our commercial speech decisions to date, we have emphasized that because disclosure requirements trench much more narrowly on an advertiser's interests than do flat prohibitions on speech, “[warnings] or [disclaimers] might be appropriately required . . . in order to dissipate the possibility of consumer confusion or deception.” . . .

We do not suggest that disclosure requirements do not implicate the advertiser's First Amendment rights at all. We recognize that unjustified or unduly burdensome disclosure requirements might offend the First Amendment by chilling protected commercial speech. *But we hold that the advertiser's rights are adequately protected as long as disclosure requirements are reasonably related to the State's interest in preventing deception of consumers.*

471 U.S. at 650-651 (emphases, ellipses and bracketed text added, citations omitted).

More recently, this “reasonable relationship” was applied in *National Elec. Mfrs. Ass’n v. Sorrell*, 272 F.3d 104 (2d Cir. 2001). In *Sorrell*, the court considered the constitutionality of a Vermont statute which mandated disclosure of the mercury content of mercury-containing light bulbs and directions as to hazardous waste disposal. In rejecting a First Amendment challenge to the law, the court noted that “[c]ommercial

disclosure requirements are treated differently from restrictions on commercial speech because mandated disclosure of accurate, factual, commercial information does not offend the core First Amendment values of promoting efficient exchange of information or protecting individual liberty interests. *Such disclosure furthers, rather than hinders, the First Amendment goal of the discovery of truth* and contributes to the efficiency of the ‘marketplace of ideas.’” *Id.* at 114 (emphasis added).

The court that decided *Sorrell* was the same court that decided the earlier case of *Int’l Dairy Foods Ass’n v. Amestoy*, 92 F.3d 67 (2d Cir. 1996), upon which Plaintiffs rely herein. In *Amestoy*, the court struck down a Vermont regulation that mandated disclosure of the use of rbST in dairy cows. *Id.* at 69. The Vermont regulation, however, had nothing to do with preventing consumer deception. As the court explained in *Sorrell*, the *Amestoy* decision “was expressly limited to cases in which a state disclosure requirement is supported by no interest other than the gratification of ‘consumer curiosity.’” *Sorrell*, 272 F.3d at 115 n.6. Since the Rule being challenged in this case is directed to preventing consumer deception, and not merely to satisfying “curiosity,” *Amestoy* is inapplicable.

Applying *Zauderer*’s reasonableness standard, it is apparent that the Rule passes the test. The mandated FDA disclosure is, first of all, indisputably true. As the FDA Interim Guidance itself explains, the FDA *has* determined that no significant difference has been shown between milk from rbST-treated and non-rbST treated cows. 59 Fed. Reg. 6279-80 (Feb. 10, 1994). This fact is not in dispute.

Individual processors and consumers may, of course, choose to quarrel with the FDA’s determination, although the FDA’s conclusions have already been upheld against

a legal challenge. *See Stauber v. Shalala*, 895 F.Supp. 1178 (W.D. Wis. 1995). As to the processors, of course, any such disagreement with the FDA's conclusions is belied by the fact that many processors, as Plaintiffs acknowledge, are already including the FDA disclosure on their labels and have been doing so for years (albeit in a different format). More importantly, however, whatever skepticism a processor or consumer might have regarding the FDA's conclusions is rendered irrelevant to the legal issue presented here because of the careful manner in which the Rule is enacted.

The Rule does *not* require processors to inform consumers that *they* have determined that there is no difference between the milk of rbST-treated and non-rbST-treated cows, nor does it require them to flatly state that such findings are true. Rather, the Rule requires processors to state the indisputable fact that the FDA (which is of course, as noted in *Stauber*, a government agency charged with protecting food safety and which carefully reviewed all of the scientific evidence available) has made such a determination. If an individual consumer distrusts the FDA, he or she is free to disregard its findings. This does not in any way alter the fact that consumers will at least be informed of the FDA's findings and will not be misled, either by silence or a hard-to-locate disclaimer buried somewhere else on the container label, into believing that such a scientific difference has been shown to exist.

Plaintiffs complain not only of the requirement that the disclosure be included on the label, but also of the requirement that the disclosure be contiguous to the rbST claim itself and in a format which reasonably assures that it will be seen and read by consumers. As the Affidavit of Lewis Jones demonstrates, however, this requirement is actually not difficult to comply with. To date, 11 processors have already submitted 42

labels to the ODA which have been found to comply with the Rule. (Jones Affidavit ¶ 6.) What Plaintiffs actually seek is the right to effectively undermine the Rule by diminishing the visibility of the disclaimer, through font size, color, location, and other means.

Plaintiffs themselves assert that milk from rbST-treated cows seems to enjoy a commercial advantage in today's marketplace. If so, it is reasonable to conclude that at least some consumers actively seek out non-rbST treated products over a competitor's products in the belief that there *is* a difference between the two. While consumers have a right to that belief, it is the ODA's responsibility to make sure that consumers are not being *mised* into that belief by being denied important information about the products as a result of the absence or obscurity of the disclaimer on the label.

As the foregoing discussion demonstrates, including the truthful FDA-disclosure statement is reasonably related to the Ohio's bona fide interest in preventing consumers from being misled regarding the products they consume. Accordingly, the Rule fully satisfies the *Zauderer* test and does not in any way infringe upon the First Amendment rights of dairy processors.

2. The Rule's prohibition of false or misleading composition claims on dairy labels does not violate Plaintiffs' First Amendment rights.

As noted above, the Rule addresses the issue of composition claims differently than production claims. This portion of the Rule (indeed, the entire Rule) is constitutional in that it does not infringe upon any First Amendment rights of the Plaintiffs.

It has been well-established by *Central Hudson* that false or misleading commercial speech is not protected under the First Amendment. This is the first prong of the *Central Hudson* analysis, 447 U.S. at 566, and is the only prong required to defeat the Plaintiffs' First Amendment arguments.

As discussed above, the composition claims referenced in paragraph (C) of the Rule are misleading, and some claims (such as "hormone free") are completely false. Unfortunately, the limits of science are such that it is currently impossible to verify composition claims regarding the presence or absence of rbST compounds in milk. It is likewise misleading, even if technically true, to advertise on a dairy label the absence of a compound which is not allowed in any milk, anywhere. To illustrate the point: a label that states milk is "radiation-free" might be true, but it would also be misleading by slyly implying that a competitor's milk *might be* radioactive if it did not state otherwise. The circumstances addressed by the Rule with regard to antibiotics and pesticides are even more serious than the "radiation" example, since a consumer is far less likely to be aware of the fact that all of the milk on a grocery store shelf is tested to verify that it has no detectable antibiotics. Viewed in this light, a label claim declaring that the milk is free of antibiotics actually casts an indirect, and false, aspersion against all other dairy products offered for sale to consumers without such a claim. The Rule is therefore supported not only by the strong state interest in preventing consumer deception, but also by the state's reasonable interest in preventing false and damaging accusations against wholesome agricultural products.

3. **Even if the label claims addressed in the Rule were not misleading, the Rule does not violate the First Amendment because the Rule directly advances a substantial state interest in a narrowly drawn fashion.**

While *Central Hudson* enunciated a “four prong” test to determine if a state law infringes upon commercial free speech, it is more accurate to characterize the test as a “one-prong plus three-prong” test, since a regulation which passes the first prong (*i.e.*, whether the regulation restricts false or misleading speech, as with the Rule herein) is constitutional, then there is no need to consider the remaining three prongs (*i.e.*, whether (2) the government interest is substantial, (3) the regulation directly advances the governmental interest, and (4) the regulation is not more extensive than is necessary to serve that interest). Because Plaintiffs argue all four prongs in their briefs and dispute that the regulated language is misleading, Defendant will show in the discussion below that the Rule also satisfies the remaining *Central Hudson* prongs even if the regulated claims were not misleading.

Ohio has a substantial interest in ensuring that consumers receive accurate information about the products they consume.

IDFA acknowledges that a governmental interest in ensuring the accuracy of consumer information may be “substantial” for purposes of evaluating a regulation under *Central Hudson*. IDFA Br. p. 17 (citing *Edenfield v. Fane*, 507 U.S. 761, 769 (1993)). IDFA then proceeds to make the puzzling argument that if the regulation is “aimed at more,” the interest is no longer substantial. IDFA’s argument breaks down because it misinterprets comments by Director Boggs and Governor Strickland in such a fashion as to confound the apparent purpose of the Rule -- namely, to ensure that consumers receive accurate product information.

Specifically, IDFA refers to a statement by the Director that the Rule is intended to provide consumers with “accurate and balanced” information – a reference in a letter by the Director that the Rule is intended to ensure that consumers receive “only the most accurate information” and that members of the public have “the information necessary to make an informed decision”; and a reference in the Governor’s Executive Order implementing the Emergency Rule (not the actual Rule currently in place) stating that the Director’s labeling authority should be implemented in a manner which “maximizes consumer information and choice.” IDFA Br. pp. 16-17. One would not think that these would be considered inconsequential or controversial governmental objectives, but IDFA tries to portray these comments as elements of a governmental campaign to impose improper control over the flow of information.

The comments are nothing of the sort. Viewed as a whole and in the context of the entire Rule, they simply describe the substantial and proper interest of the state in ensuring accurate consumer information. The phrase “only the most accurate information,” for example, is simply another way of saying “information which is not inaccurate or misleading.” The phrase “maximizing consumer information and choice” is the equivalent of “accommodating the free flow of accurate product information.” The term “balanced information” is synonymous with “truthful information which is not presented in a misleading fashion.” All of these comments return to the same point -- namely, that the Rule is intended to advance the proper and substantial governmental objective of ensuring the accuracy of consumer information.

The Rule directly advances the governmental interest.

For composition claims, the Rule restricts only those claims which are false or misleading. This directly and immediately serves the interest of ensuring accurate consumer information by preventing consumers from being given false claims, misleading claims, and claims that are impossible to verify. For production claims, the Rule advances the state's interest by requiring the disclosure of a truthful statement referencing pertinent findings by the FDA that effectively removes the possibility that consumers will be misled by the otherwise implied assertion that milk from non-rbST-treated cows is superior to other milk, while at the same time facilitating the transmission of this information which Plaintiffs claim consumers want to have.

The Rule is narrowly drawn to accomplish its objective.

The Rule is carefully drafted and narrowly tailored to meet the foregoing objectives. First, the Rule does *not* prohibit any claim regarding the non-use of rbST in the production of the milk. On the contrary, it provides a reasonable mechanism to convey this very information in such a manner as to ensure that the message will not be misleading.

Second, the Rule does *not* prohibit all composition claims regarding milk. Rather, it describes and restricts only those claims that are either false or inherently misleading.

Third, the Rule does *not* require processors to attest to or “second” the FDA's findings, but simply to report them accurately for that they are – the carefully considered conclusions of the appropriate regulatory authority following a thorough review of the available science.

Fourth, the Rule does *not* require the disclaimer to be in the same font size as the claim. Following extensive input from industry sources, the Rule allows the disclaimer to be only one-half the font size of the claim (at least 7-point font), greatly increasing the ease of compliance. (*See* Affidavit of Lewis Jones.)

In each of these respects, the Rule has been crafted in such a way as to accomplish the objective without placing an undue burden on the dairy industry.

For the foregoing reasons, the Rule does not violate Plaintiffs' commercial speech rights under the First Amendment.

B. The Rule does not violate the dormant Commerce Clause of the United States Constitution because it is non-discriminatory and does not excessively burden interstate commerce.

The "dormant" aspect of the Commerce Clause in the United States Constitution has been described as "a self-executing limitation on the power of the States to enact laws imposing substantial burdens on [interstate] commerce." *E. Ky. Res. v. Fiscal Court of Magoffin County, Ky.*, 127 F.3d 532, 539 (6th Cir. 1997) (citing *South-Cent. Timber Dev. Inc. v. Wunnicke*, 467 U.S. 82 (1984)). The Clause's purpose "is to prohibit outright economic protectionism or regulatory measures designed to benefit in-state economic actors by burdening out-of-state actors." *Id.* at 540 (citing *New Energy Co. v. Limbach*, 486 U.S. 269, 273 (1988)); *see also Wyoming v. Oklahoma*, 502 U.S. 437, 454 (1992) (dormant Commerce Clause prohibits "regulatory measures designed to benefit in-state economic interests by burdening out-of-state competitors.").

Implementing these principles, courts evaluate dormant Commerce Clause challenges in a two-step analysis: First, the court determines whether the state regulation "directly burdens interstate commerce or discriminates against out-of-state interests."

Lenscrafters, Inc. v. Robinson, 403 F.3d 798, 802 (6th Cir. 2005) (citing *E. Ky. Res.*, 127 F.3d at 540). If it does, the regulation is *per se* invalid, unless the state “can demonstrate, under rigorous scrutiny, that it has no other means to advance a legitimate local interest.” *C&A Carbone, Inc. v. Clarkstown*, 511 U.S. 383, 392 (1994). If the state regulation does not discriminate, then the court must decide whether the burdens on interstate commerce are “clearly excessive in relation to the putative local benefits.” *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970).

As explained below, the Rule comports with the dormant Commerce Clause because, contrary to Plaintiffs’ arguments, it does not (1) directly regulate interstate commerce in dairy products outside Ohio, (2) impose inconsistent regulatory burdens on interstate commerce, (3) discriminate against out-of-state dairy industry members in favor of Ohio farmers, or (4) impose upon interstate commerce an unreasonable burden compared to the local benefits.

1. The Rule was not enacted for a protectionist purpose, does not discriminate in any way against out-of-state economic interests, and places no direct burdens on interstate commerce.

The Rule easily passes the first step of the dormant Commerce Clause analysis. On its face, the Rule is completely even-handed with regard to in-state and out-of-state parties. It simply applies to dairy products which are offered for sale in Ohio. The Rule draws no distinction whatever between milk produced in Ohio or in other states, or between dairy products which are processed either within or outside Ohio. Its labeling requirements and restrictions are identical for both in-state and out-of-state industry participants. “Discrimination” in this context is a well-defined term, and means “differential treatment of in-state and out-of-state economic interests that benefits the

former and burdens the latter.” *Maharg, Inc. v. Van Wert Solid Waste Management Dist.*, 249 F.3d 544, 550 (6th Cir. 2001) (citing *Oregon Waste Mgmt, Inc. v. Dep’t of Env’tl. Quality*, 511 U.S. 93, 99 (1994)). In this case, there is no evidence of such differential treatment.

Nor is there any evidence that the Rule was enacted for any protectionist purpose. As discussed elsewhere in this Memorandum and explained in the attached Affidavit of Robert J. Boggs, the Rule’s purpose is to ensure that Ohio consumers receive truthful, non-misleading information regarding the dairy products that they consume. (Boggs Affidavit ¶ 7.) Given the even-handed manner in which the Rule is structured, it is difficult to see how it could have any “protectionist” aim. Even if Plaintiffs’ claim that the Monsanto Company (the marketer of the rbST product Posilac) is somehow behind the Rule as part of a nationwide campaign to protect sales of its product, were true (it is not), that does not make the Rule “protectionist” for purposes of the dormant Commerce Clause.

Plaintiffs argument that the Rule was intended to protect the interests of Ohio dairy farmers, by creating an rbST-friendly environment for milk production, breaks down completely when placed under scrutiny. It may well be that some Ohio dairy farmers would prefer to continue to use rbST to supplement their cows and increase their milk production, but find it difficult to market milk from rbST-supplemented cows in the current marketplace. Such farmers might prefer to see a ban on any reference to rbST use (or non-use) on Ohio dairy labels. However, the Rule does not discriminate in favor of such farmers, for two obvious reasons: (1) the hypothetical rbST-using dairy farmer in Ohio is on exactly the same legal footing as a similar farmer outside of Ohio, so there is

no discriminatory purpose or impact whatever; (2) as noted elsewhere, the Rule does *not* ban any reference to rbST use on dairy labels, so there is no mechanism in the Rule to allow an Ohio dairy farmer (or any other dairy farmer) to use rbST “under the radar.”

In light of these facts, Plaintiffs principally argue that the Rule directly impacts interstate commerce by allegedly (1) regulating extraterritorial commercial transactions, (2) subjecting out-of-state producers and processors to inconsistent regulations, and (3) unjustly “isolating” the Ohio economy from the national market. None of these contentions has merit.

It is neither surprising nor unusual if a state regulation, enacted to protect the welfare of the citizens of the state, exerts some impact on interstate commerce. As the Supreme Court stated in *Milk Control Bd. v. Eisenberg Farm Prods.*, 306 U.S. 346 (1939), “[o]ne of the commonest forms of state action is the exercise of the police power directed to the control of local conditions and exerted in the interest of the welfare of the state’s citizens. *Every state police statute necessarily will affect interstate commerce in some degree, but such a statute does not run counter to the grant of Congressional power merely because it incidentally or indirectly involves or burdens interstate commerce.* . . . These principles have guided judicial decision for more than a century.” *Id.* at 351-352 (emphasis added).

The impacts which Plaintiffs complain of are not “direct burdens” on interstate commerce, but at most *indirect* impacts which are neither unusual nor unconstitutional. The Rule does not, for example, regulate interstate commerce taking place entirely outside Ohio in anything approaching the manner which courts have found to violate the Commerce Clause. Plaintiffs rely heavily upon *Healy v. The Beer Institute*, 491 U.S. 324

(1989), for the proposition that a rule which has the effect of controlling extraterritorial transactions is unconstitutional under the dormant Commerce Clause. A review of the law struck down in *Healy*, however, shows it to be a fine example of what the Rule in this case is *not* – namely, an attempt to control extraterritorial commercial transactions in other states.

In *Healy*, a Connecticut statute attempted to lower in-state beer prices (as compared to the prices in three bordering states) by requiring brewers and beer importers to post their prices once a month and to affirm that their prices to in-state wholesalers would be no higher than the prices charged in the bordering states at the time of the Connecticut posting. *Id.* at 326-27. Finding that the statute had the direct effect of controlling beer prices in the neighboring states and discriminated against interstate brewers and importers (as opposed to their intrastate counterparts), the Court unsurprisingly found this to violate the Commerce Clause. *Id.* at 339-41.

Healy is relevant only as a stark contrast to the utterly different intent and effect of the Rule challenged in this case. Far from exerting control over extraterritorial transactions, the Rule addresses only the label requirements for dairy products sold within Ohio. Nothing on the Rule's face mandates or regulates any label on products offered for sale in other states. If the Rule has any effect in other jurisdictions, it is at most an indirect impact arising only from the choice of dairy processors operating in other states to market their products with a single label nationwide.

If Plaintiffs' argument were accepted, the effect would be to block virtually any exercise of the traditional state police power to protect the interests of its citizens with regard to label requirements for nationally-marketed commercial items. That has never

been the law, and could not be the intent of the dormant Commerce Clause, as it would effectively remove states from enacting label regulations altogether.

Similarly, *Healy* provides no support for Plaintiffs' argument that the Rule improperly multiplies the likelihood that dairy processors will be subject to inconsistent obligations. It is possible that, unless and until Congress enacts a national standard regarding rbST claims (as it has for the use of the term "organic" in the Organic Food Production Act discussed below), dairy processors will face the prospect of differing label regulations in different states. That is not, however, the fault of the Rule. States have traditionally regulated such issues as food labels on items offered for sale within the state. *Kellogg Co. v. Mattox*, 763 F. Supp. 1369, 1379 (W.D. Tx. 1991). This was not only recognized but expressly relied upon by the FDA when it issued its Interim Guidance on rbST claims. *See* 59 Fed.Reg. 6279-80 (Feb. 10, 1994).

In effect, Plaintiffs argue that Ohio should basically abdicate its responsibility to regulate labels and try instead to form a *de facto* coalition of similar rules with the other states in order to make up for the lack of a national standard on this issue, thereby facilitating national marketing efforts of Plaintiffs' members. This argument turns the traditional state regulatory rule on its head, and is not what *Healy* requires. To the contrary, *Healy* held that the "Commerce Clause protects against inconsistent legislation arising from the *projection of one state regulatory regime into the jurisdiction of another State.*" 491 U.S. at 337 (emphasis added). In short, the Connecticut beer-price reduction scheme at issue in *Healy*, which directly linked acceptable Connecticut beer prices to the prices offered in bordering states, was an improper attempt to project Connecticut's

regulatory scheme beyond its borders into the adjoining state. Nothing in the Rule at issue in this case is remotely similar to this scheme.

Plaintiffs' argument that the Rule improperly discriminates against interstate commerce by isolating the Ohio economy from the national market is also unavailing, and misconstrues not only the Rule but also the applicable case law. Plaintiffs' reliance upon *Hunt v. Washington State Apple Adver. Comm'n*, 432 U.S. 333 (1977) is misplaced. In *Hunt*, a North Carolina statute prohibited closed containers of apples shipped into the state from bearing state grades or classifications. Washington State growers challenged the law as an unlawful restraint on interstate commerce. While the Supreme Court found the law violated the dormant Commerce Clause, it did so for reasons which are simply inapplicable to the facts of this case.

The *Hunt* Court noted that the North Carolina law not only burdened the sales of Washington State apples but actively discriminated against them. 432 U.S. at 348-354. This conclusion is based upon facts unique to *Hunt* and not present in this case. First, the North Carolina law increased the cost of Washington apple growers but left the cost of North Carolina growers alone, since they were not using state grades. By contrast, the Ohio Rule's requirements apply equally to both Ohio and out-of-state dairy farmers and processors. Plaintiffs respond with the illogical argument that Ben & Jerry's, Tillamook, and Shamrock have been selling product in Ohio with "non-use" claims for years, whereas Ohio farmers have allegedly not been asked for non-use declarations by their processors in the past. This argument overlooks the fact that (1) Ohio farmers are now being asked for such declarations, so the parties are at least now on an equal footing, and, as a result, (2) the cost of compliance is no greater or lesser anyway. All processors, both

within and beyond Ohio, will be required to sell products with labels which conform to the Rule, and it makes no difference to their cost of compliance whether their previous labels contained rbST claims or not.

Second, the evidence in *Hunt* indicated that Washington apple growers had established a state grading system which exceeded national standards and had gained national acceptance. *Hunt*, 432 U.S. at 336. The North Carolina statute therefore had the effect of enforcing a “downgrade” on the Washington apples. There is no parallel to this factor in this case.

Third, the North Carolina law applied only to closed containers of apples, a distinction which singled out Washington apples from North Carolina apples, since only the former were sold in closed containers. Again, this factor is totally absent in this case. There is no evidence of any disparity between Ohio dairy products and out-of-state dairy products with regard to the manner in which they are packaged for sale.

Based upon all of these factors, it is not surprising that the *Hunt* Court found the North Carolina law improperly discriminated against interstate commerce. However, Plaintiffs fail to demonstrate any basis to draw the same conclusions with regard to the Rule that they challenge in this case.

2. Any incidental burden which the Rule may place upon interstate commerce is not clearly excessive in relation to the local benefit.

Because the Rule is even-handed and does not discriminate against or place a direct burden on interstate commerce, the remaining issue for this Court to determine is whether the incidental burden placed upon interstate commerce is “clearly excessive” in

comparison to the local benefit incurred. *Pike*, 397 U.S. at 142. As discussed below, the Rule easily passes this test as well.

The first half of the balancing test, *i.e.*, the incidental impact on interstate commerce, is truly minimal. While it is true that some processors who choose to make claims regarding the non-use of rbST will have to modify their existing labels on products intended for the Ohio market, the resultant burden on interstate commerce is very slight. The ODA has recently reviewed and approved 42 labels which are fully in compliance, including labels submitted by a number of processors who submitted declarations in support of Plaintiffs in this case, complaining of the near impossibility of compliance with the Rule. (*See Jones Affidavit* ¶ 6.) While some processors may choose to use a single national label for all of their products, this is by no means required either by the Rule or by industry practice. (*Id.* ¶ 7.) In fact, milk is routinely labeled with different labels on the same production line with varying “store brand” labels, for example, and need cause no disruption of even a large processor’s business operations. Creating and maintaining labels which comply with applicable government regulations is an ordinary business expense for any company, and it falls with equal weight on the shoulders of Ohio and non-Ohio processors alike. As the Rule makes plain, dairy products offered for sale in Ohio must comply with the Rule regardless of whether the milk was produced in Ohio or in a state on the other side of the continent. Any burden that results is not a burden on “interstate commerce,” but simply a cost of doing business.

This is not the level of burden which the *Pike* Court had in mind. Indeed, *Pike* itself offers a useful example of the type of burden which is excessive. There, the Arizona official responsible for enforcing the state’s Fruit and Vegetable Standardization

Act prohibited Bruce Church, Inc. from transporting uncrated Arizona-grown cantaloupes to its facility in California for packing, relying upon the Act's requirement that cantaloupes grown in Arizona and offered for sale were to be packed in containers approved by the supervisor. As a result of this order, Bruce Church would have been forced to build a permanent facility in Arizona, expending \$200,000 (in 1968 dollars), simply to avoid shipping the cantaloupes 31 miles into California. *Pike*, 397 U.S. at 139. This case provides a vivid contrast to the minimal cost of making a minor modification to labels on dairy products offered for sale in Ohio.

The other side of the equation, the local interest advanced, is a traditional and important role of the state: ensuring that food labels are truthful and not misleading. Courts have traditionally recognized this function as a legitimate state interest. *See Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 144 (1963). Public protection of this type is in fact a bedrock responsibility of government, and far outweighs the incidental burdens which may arise as a result of the Rule. Again, *Pike* itself offers a useful basis for comparison. As the Court noted, the local benefit being advanced was nothing remotely as important as consumer protection; on the contrary, it was the attempt to burnish the reputation of other Arizona cantaloupe growers by having the name of Arizona placed on Bruce Church's high quality fruit. In other words, it was nothing more than a reach for the reflected glow of one grower's excellent produce for the benefit of other growers. As the Court aptly put it, "Although it is not easy to see why the other growers of Arizona are entitled to benefit at the company's expense from the fact that it produces superior crops, we may assume that the asserted state interest is a legitimate one. But the State's tenuous interest in having the company's cantaloupes

identified as originating in Arizona cannot constitutionally justify the requirement that the company build and operate an unneeded \$200,000 packing plant in the State.” *Pike*, 397 U.S. at 145.

As the above summary demonstrates, the facts in this case are the converse of the facts that gave rise to the *Pike* test in the first place. Whereas in *Pike* the burden on interstate commerce was great and the local benefit “tenuous” at best, this case presents a situation in which the burden on interstate commerce is slight and the local benefit compelling. For this reason, the Rule passes the test that the regulation in *Pike* itself could not.

For these reasons, this Court should find that the Rule does not violate the dormant Commerce Clause.

C. OTA’s preemption claims are without merit.

The preemption doctrine is rooted in the Supremacy Clause (Article VI, Clause 2) of the federal Constitution, *Fidelity Fed. Sav. & Loan Ass’n v. de la Cuesta*, 458 U.S. 141, 152 (1982), and “invalidates state laws that ‘interfere with, or are contrary to,’ federal law.” *Hillsborough Cty., Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 712 (1985) (quoting *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 211 (1824)). Federal preemption of state law is “an extraordinary power . . . that [courts] must assume Congress does not exercise lightly.” *Gregory v. Ashcroft*, 501 U.S. 452, 460 (1991) (ellipsis and bracketed text added).

In every preemption case, “the purpose of Congress is the ultimate touchstone.” *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (quoting *Retail Clerks Internat’l Ass’n, Local 1625, AFL-CIO v. Schermerhorn*, 375 U.S. 96, 103 (1963)). Further, “[in] all pre-

emption cases . . . [courts] ‘start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.’” *Id.* (ellipsis in original, bracketed text added) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). State laws designed to protect consumers, including food-labeling laws, “represent an exercise of the historic police powers of the States,” and are thus not preempted “in the absence of an *unambiguous congressional mandate* to that effect.” *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 146-47 (1963) (emphasis added); *see also General Motors Corp. v. Abrams*, 897 F.2d 34, 41-42 (2d Cir. 1990) (requiring “compelling evidence” of congressional intent to preempt state consumer protection laws). This judicial presumption against preemption applies to state regulations unless there has been a history of significant federal presence. *United States v. Locke*, 529 U.S. 89, 108 (2000).

Plaintiffs do not claim that federal law expressly preempts Ohio’s Rule. However, OTA claims¹ the Rule is impliedly preempted because Congress, through the Organic Foods Production Act, 7 U.S.C. § 6501 *et seq.* (1990) (“OFPA”) and attendant National Organic Program regulations, 7 C.F.R. § 205 *et seq.* (2000) (“NOP”), has completely occupied the entire field of organic labeling, leaving no room for state regulation. OTA also argues that the rule is impliedly preempted because it conflicts with the OFPA. For the following reasons, OTA’s preemption claims are without merit.

¹ Although IDFA “endorses” OTA’s preemption claim, *see* IDFA’s MSJ (Doc. 21, Case No. 2:08-CV-628) p. 43, IDFA does not make a preemption claim in its complaint.

1. Congressional regulation of organic food production, handling, and labeling is not so sweeping as to preclude states from exercising their police powers to protect consumers from the false or misleading labeling of dairy products.

Federal law may preempt state law in cases where congressional regulation of a field is so pervasive, or the federal interest is so dominant, to imply an intent to occupy the field exclusively, leaving no room for state regulation. *R.R. Ventures, Inc. v. Surface Transp. Bd.*, 299 F.3d 523, 561-62 (6th Cir. 2002). However,

[T]o ‘infer pre-emption whenever a [federal] agency deals with a problem comprehensively is virtually tantamount to saying whenever a federal agency decides to step into a field, its regulations will be exclusive. Such a rule, of course, would be inconsistent with the federal-state balance embodied in our Supremacy Clause jurisprudence.’

Moore v. Kimberly-Clark Corp., 867 F.2d 243, 245 (5th Cir. 1989) (bracketed text added) (quoting *Hillsborough Cty.*, 471 U.S. at 717).

While the OFPA and NOP may show that Congress has extensively regulated the field of organic labeling, such regulation is not so sweeping as to leave no room for Ohio to protect consumers from false or misleading labeling of dairy products. The regulation of food labeling is a field traditionally occupied jointly by the states and the federal government. *Kellogg Co. v. Mattox*, 763 F. Supp. 1369, 1379 (W.D. Tx. 1991). The FDA has often stated that states have a role to play in food labeling regulation. Charles P. Mitchell, *State Regulation & Federal Preemption of Food Labeling*, 45 FOOD DRUG L.J. 123, 127 (1990).

The purposes of the OFPA are to (1) “establish national standards governing the marketing” of organic agricultural products, (2) “assure consumers that organically produced products meet a consistent standard,” and (3) “facilitate interstate commerce in fresh and processed food that is organically produced.” 7 U.S.C. § 6501. The OFPA

further these purposes through a national organic certification program and by regulating organic labeling. *Id.* §§ 6503(a), 6504, 6505(a)(1)(A). Although the OFPA was created to be stricter than existing state organic regulations, the statute allows for state organic regulations that are as stringent as the OFPA regulations. S. REP. NO. 101-357, at 643 & 648-50 & 1290 (1990). State organic certification programs may be more restrictive than the NOP. 7 U.S.C. § 6507(b)(1).

“[B]y themselves, the OFPA and NOP simply establish a certification program for organic products.” *Partlo v. Johanns*, 2006 U.S. Dist. LEXIS 43071 at *26 (D.D.C. June 11, 2006). To be labeled as “organic,” an agricultural product must generally be produced without synthetic substances and in accordance with an organic plan agreed to by an accredited certifying agent, the producer, and the handler of the product. *Id.* § 6504. Further, § 6505 of the OFPA sets forth compliance requirements for organic certification and labeling. While these labeling requirements are detailed, they do not address false or misleading statements in dairy labeling.

To support its claim of field preemption, OTA attempts to analogize its case to *Gade v. Nat’l Solid Wastes Mgmt. Ass’n*, 505 U.S. 88 (1992), which held that a federal OSHA statute delineating state jurisdiction preempted state laws establishing an occupational health and safety standard on an issue where OSHA had already promulgated a standard, unless the state had obtained the Secretary of Labor’s approval. *Id.* at 99-100. OTA argues that, based on *Gade*, Ohio cannot regulate organic labeling because it does not have an organic program approved by the Secretary of Agriculture in accordance with the NOP. *See* 7 C.F.R. § 205.620. OTA also points to a statement in the Senate Report that encourages the organic industry to inform consumers about all

materials used in organic production, *see* S. REP. NO. 101-357, at 300 (1990), but does not address organic producers' gratuitous claims regarding "rbST free" or "hormone free" milk. Despite some consumer perception, in the absence of evidence that rbST milk is unsafe, there is no consumer-protection rationale to misbrand products with such labels. *See Stauber v. Shalala*, 895 F. Supp. 1178, 1193 (W.D. Wis. 1995).

The Rule does not purport to, or effectively, regulate organic labeling of agricultural products. Nothing in the Rule purports to expand, modify, or limit the conditions for or use of the "organic" label on agricultural products. Rather, it simply defines certain statements and claims on dairy labels regarding rbST and other hormones as false or misleading under certain circumstances, regardless of whether such products are labeled "organic." *See* Ohio Admin.Code § 901: 11-8-01 (B)-(D). Also, the Rule does not run afoul of the OFPA because it does not prohibit organic producers and handlers from informing consumers about materials used in organic production—only from adding gratuitous statements about hormones not used in production.

Further, the Rule is consistent with Food, Drug, and Cosmetic Act interim labeling guidelines, which, as interpreted by the FDA, flatly prohibit as false and misleading labels claiming milk is "hormone free" or "bST free." *See* 59 Fed.Reg. 6279-80 (Feb. 10, 1994). These guidelines clearly show that the FDA believes that states have not been completely excluded from the field of regulating rbST milk labels. Dan L. Burk, *The Milk Free Zone: Federal & Local Interests in Regulating RecombinantbST*, 22 COLUM. J. ENVTL. L. 227, 268 (1994).

OTA's argument that the Rule is unconstitutional because Ohio does not have an organic program approved by the Secretary of Agriculture in accordance with 7 C.F.R. §

205.620(a) fails because the NOP restrictions do not require states to obtain such approval in order to regulate false or misleading dairy labeling. Also, the Rule does not prohibit or interfere with OTA members (or anyone) from informing customers that their products are organic. The Rule simply either prohibits additional false and misleading information (such as “rbST free” statements, *see* Ohio Admin.Code § 901:11-8-01(C)), or requires additional information (where the label claims that “this milk is from cows not supplemented with rbST,” *see* § 901:11-8-01(B)).

OTA does not show that the federal regulatory schemes leave no room for the states to exercise their police powers to protect consumers by regulating false or misleading dairy labeling. Accordingly, the Rule is not impliedly preempted by the OFPA. *See Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 146-47 (1963).

2. The Rule does not conflict with the OFPA’s purposes of establishing national organic standards, because there is no evidence Congress intended to prevent states from protecting consumers from false and misleading labels on organic products.

Federal law also preempts state law where the two conflict so that it is physically impossible to comply with both laws simultaneously, or where enforcement of the state law stands as an obstacle to the accomplishment of the full purposes and objectives of Congress. *Fla. Lime*, 373 U.S. at 142-43; *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941); *see also Barnett Bank of Marion Cty., N.A. v. Nelson*, 517 U.S. 25, 31 (1996) (allowing states to regulate national banks where the state law does not prevent or significantly interfere with the bank’s exercise of its powers). Mere differences between federal and state law are not sufficient to find conflict preemption. *Motor Vehicle Mfrs. Ass’n of the U.S., Inc. v. Abrams*, 899 F.2d 1315, 1322 (2d Cir. 1990).

OTA does not argue that compliance with both the OFPA and the Ohio Rule is physically impossible—only that the Rule stands as an obstacle to the accomplishment of the OFPA’s purpose to “establish national standards governing the marketing” of organic agricultural products. 7 U.S.C. § 6501.² OTA cites to *Lever Bros. Co. v. Maurer*, 712 F. Supp. 645 (S.D. Ohio 1999), where this Court found, *inter alia*, that an Ohio statute that absolutely prohibited listing the word “butter” as a product ingredient in a butter substitute obstructed the objectives of federal food-labeling laws – to avoid food misbranding and to inform consumers of the actual characteristics and properties of food products. *Id.* at 651. The Court also found that compliance with both the federal laws and the Ohio statute was impossible, because the federal laws required labels to list the ingredients contained in the food product. *Id.* The Court also concluded that the state law did not prevent consumer deception. *Id.* at 653.

The law invalidated in *Lever Bros.* is a far cry from the Rule challenged in this case. The Rule does not prohibit organic labeling that the OFPA compels. Further, nothing in the OFPA or NOP requires organic products to contain the “rbST free,” “rbGH free,” labels that the Rule specifically prohibits. Thus, compliance with both laws is physically possible.

Further, the Rule does not obstruct the OFPA’s purpose to “establish national standards governing the marketing” of organic agricultural products. The Rule in no way prohibits or interferes with organic producers’ compliance with livestock handling requirements. *See* 7 C.F.R. § 205.237-239. And, there is no evidence that national

² OTA does not argue that the challenged Ohio rule interferes with the other purposes of the OFPA, which are to “assure consumers that organically produced products meet a consistent standard,” and to “facilitate interstate commerce in fresh and processed food that is organically produced.” 7 U.S.C. § 6501(2) & (3).

organic marketing standards are intended to preclude states from protecting consumers from false and misleading dairy labeling based on overwhelming evidence that rbST-treated milk is safe. *See Stauber*, 895 F. Supp. at 1193.

For these reasons, the Rule does not conflict with the OFPA, and is therefore not preempted.

D. The Rule’s use of the word “may” does not render it unconstitutionally vague, because the term is properly construed as mandatory and thus not encouraging or allowing for arbitrary or discriminatory enforcement.

The void for vagueness doctrine is an outgrowth of the Due Process Clause of the Fourteenth Amendment, *United States v. Williams*, 128 S.Ct. 1830, 1845 (2008), and only requires that a rule give fair warning of prohibited conduct. *Akridge v. Wilkinson*, 351 F. Supp. 2d 750, 769 (S.D. Ohio 2004) (citing *Colten v. Ky.*, 407 U.S. 104, 110 (1972)). The standards for a vagueness claim are whether the challenged law (1) gives the person of ordinary intelligence a reasonable opportunity to know what is prohibited, and (2) provides explicit standards for those who apply them, to prevent arbitrary and discriminatory enforcement. *Grayned v. City of Rockford*, 408 U.S. 104, 109 (1972). Greater leeway is given to civil laws than to criminal laws, because the consequences of imprecision are qualitatively less severe. *Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 498-99 (1982).

Relying on *Grayned*, OTA³ claims that the Rule is unconstitutionally vague because it uses the word “may,” instead of “must” or “shall,” for certain labeling criteria. Specifically, Ohio Admin.Code § 901:11-8-01(B) provides that a dairy label which contains a claim “this milk is from cows not supplemented with rbST” may be considered

³ IDFA does not raise a vagueness challenge in its motion for summary judgment.

misleading; while § 901:11-8-01(D) provides that labels which indicate the absence of a compound not permitted by the FDA to be present in any dairy product may be considered false or misleading.

Grayned, however, does not support OTA's argument. In that case, the Supreme Court simply upheld against a vagueness challenge an anti-noise ordinance which provided that no person adjacent to a building in which a school or class is in session "shall" willfully make or assist in making noise that disturbs or tends to disturb the peace or order of the school or class session. 408 U.S. at 108-09. The Court said nothing about whether the use of the word "may" (instead of "shall" or "must") in state laws creates an unconstitutional risk of arbitrary and discriminatory enforcement.

Although use of the word "may" in statutes and rules customarily connotes discretion, *see Jama v. Immigration & Customs Enforcement*, 543 U.S. 335, 346 (2005), the word should be construed as mandatory where "public interests are involved, and the public or third persons have a claim *de jure* that the power conferred should be exercised, or whenever something is directed to be done for the sake of justice or the public good" 59 Corpus Juris pp. 1082-1085 (ellipsis added). There can be no dispute that the Rule is designed to further the public interest and public good by protecting consumers from false or misleading dairy labeling.

Further, use of the word "may" does not render a state law unconstitutionally vague when the word is used to express ability or power. In *State v. Mutschler*, 65 P.3d 469 (Ariz. App. 2003), the Arizona Court of Appeals upheld against a vagueness challenge a city ordinance that defined a prohibited "live sex act business" as "any business that in which one or more persons may view, or may participate in, a live sex act

for consideration.” *Id.* at 471 (quoting Phoenix City Code § 23-54(B)(3) (2002)). The court found it was clear from the ordinance that the undefined word “may” is able to be replaced by the word “can,” and was used in the ordinance to “express ability or power.” *Id.* at 472 (quoting *Webster’s New World College Dictionary* 889 (2000)). Likewise, in this case, the challenged rule’s use of the undefined word “may” is appropriately construed as “can,” without encouraging or risking arbitrary or discriminatory enforcement.

Finally, when a law is susceptible of more than one permissive construction, courts must “construe the [law] to avoid [constitutional] problems” if it is “fairly possible.” *Boumediene v. Bush*, 128 S.Ct. 2229, 2271 (2008) (first bracketed text added) (quoting *INS v. St. Cyr*, 533 U.S. 289, 299-300 (2001) (quoting *Crowell v. Benson*, 285 U.S. 22, 62 (1932))). Accordingly, if this Court finds that construing the word “may” as discretionary renders the rule unconstitutional, it should construe the term as mandatory and thus avoid any question of the rule’s constitutionality.

V. CONCLUSION

For these reasons, Defendant’s motion for summary judgment on all claims should be granted, while Plaintiffs’ motions for summary judgment should be denied.

Respectfully submitted:

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CERTIFICATE OF SERVICE

I certify that on August 25, 2008, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all CM/ECF participants.

/s/ William J. Cole
WILLIAM J. COLE